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ATTORNEY'S DOCKET NO.: 2002906-0002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mitchell, et al. Examiner:
Serial No.: 09/931,506 Art Unit: 1636
Filed: August 16, 2001
For: DECELLULARIZED TISSUE ENGINEERED CONSTRUCTS AND TISSUES

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Sir:

TRANSMITTAL LETTER

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Enclosed are the following documents:

1. Form PTO-1449 (2 pages);
2. Information Disclosure Statement (5 pages);
3. Cited Art (32 references); and
4. Return Postcard

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

Monica R. Gerber

Monica R. Gerber, M.D., Ph.D.
Reg. No. 46,724

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Dated:

3405724

I hereby certify that this correspondence is being deposited with the United States Postal service as first class mail in an envelope addressed to Assistant Commissioner For Patents, Washington, D.C. 20231
on *June 20, 2002*
[Signature]

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**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants request consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

(Select A, B, C or D below)

- A. ☒ This Information Disclosure Statement has been filed:
1. ☐ within three months of the filing date of the above identified U.S. Patent application other than a continued prosecution application under § 1.53(d);
 2. ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International application;
 3. ☒ before the mailing date of the first Office Action on the merits in the above-identified application; or
 4. ☐ before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

No fee or certification is required.

B. ☐ This Information Disclosure Statement has been filed more than three months after the filing date of the present application and after the mailing date of the first Office Action, but before the mailing date of any of a final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application, and:

(check 1 or 2 below)

1. ☐ The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed, OR
2. ☐ The Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that

(check a or b below)

- a. ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or
- b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.

C. ☐ This Information Disclosure Statement has been filed after the mailing date of either a Final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311 and on or before payment of the Issue Fee.

1. The Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that:
 - a. ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or
 - b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a

counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement; AND

2. The Petition Fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

D. ☐ This Information Disclosure Statement does not comply with any of the provisions set forth above, or is being submitted after the payment of the issue fee; however, Applicants respectfully request that the Statement be placed in the above-referenced file.

PART II - 37 CFR § 1.98 Content of Information Disclosure Statement:

☐ A. Applicants hereby make of record in the above-identified application all patents, publications, applications or other information submitted for consideration by the Office listed on the attached form PTO-1449 (modified). The order of presentation of the patents, publications, applications or other information should not be construed as an indication of the importance. Applicants have provided a legible copy of:

- each U.S. patent application publication;
- each U.S. foreign patent;
- each publication or that portion which caused it to be listed;
- each pending U.S. application (including the application specification including the claims and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion); and
- other information or that portion which caused it to be listed.

For each patent, publication, or other information listed that is not in the English language, the following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

Alternatively, if a written English-language translation of a non-English-language document, or portion thereof, is within the possession, or control of, or is readily available to any individual designated in § 1.56(c), a copy of the translation is provided herein as identified:

[] B. The Applicants hereby make the following additional information of record in the above-identified application:

PART IV: Remarks

A copy of each of the above-identified U.S. and foreign patent(s), publication(s), application(s) or other information submitted is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s), publication(s), application(s), or other information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, Applicants make no representation that a search has been performed, of the extent of any search performed, or that more material information may not exist.

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited materials. An early and favorable action is hereby requested.

Respectfully submitted,

Monica R. Gerber

Monica R. Gerber, M.D., Ph.D.
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53 State Street
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on *June 20, 2002*